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GUILFORD PHARMACEUTICALS CO.  
FOLEY & LARDNER  
3000 K STREET, NW  
WASHINGTON, DC 20007-5143

In re Application of :  
Barbara S. Slusher et al :  
Serial No.: 09/866,961 : PETITION DECISION  
Filed: May 30, 2001 :  
Attorney Docket No.: 264/239 :

This is in response to the petition under 37 CFR 1.181, filed July 19, 2004, requesting withdrawal of the Final Office action.

A review of the file history shows that the examiner mailed a non-Final Office action to applicants on February 14, 2003. Applicants replied to this Office action on May 12, 2003, canceling claims 1-24 and 27-49, amending claim 25 and presenting new claims 50-58 and responding to the outstanding rejections. The examiner mailed a new non-Final Office action to applicants on September 16, 2003, setting forth a new rejection of the pending claims. Applicants (contrary to the petition assertion) replied to this Office action on October 17, 2003. (Copy enclosed) The response of October 17, 2003, is identical to the reply made May 12, 2003. A further response was made December 16, 2003, which specifically refers to the September 16, 2003, Office action. The examiner then mailed a Final Office action to applicants on January 29, 2004, maintaining the rejection of the Office action of September 16, 2003. Applicants filed an amendment in response to the Final Office action on April 8, 2004. The amendment (argument only) makes no request to withdraw the finality of the Final Office action. The examiner mailed an Advisory Action to applicants on July 7, 2004, indicating entry of the amendment, but failure to overcome the rejection of record. Applicants also initiated a telephone interview with the examiner's supervisor (see interview summary mailed August 9, 2004) seeking withdrawal of the Final Office action and Advisory Action. This petition was filed prior to the interview.

As seen from the above chronology of Office actions and responses, conduct of prosecution was proper and the finality of the last Office action was proper. Applicants claim that no response was filed on October 17, 2003. However the application file record shows a response being filed on that date which was initially accepted as a response to the Office action of September 16, 2003. The later response of December 16, 2003, was a more proper reply to the Office action. Had no response been filed the application would have become abandoned on March 17, 2004. However, as can be seen from the record responses were made which required the examiner to reexamine the application and issue a new, in this case Final, Office action. In view of the

above, no good or sufficient reason has been given for withdrawal of the finality of the Office action mailed January 29, 2004.

Further, a request to withdraw an improper Office action by an examiner under 37 CFR 1.181 must be filed within two months of the action complained of (37 CFR 1.181(f)). Such appears not to be the case here. The request to have the Final Office action withdrawn was not made in the response filed April 8, 2004, as it should have been, but appears to have first been filed six months after the actions was taken in this petition and can therefore also be dismissed as untimely.

The petition is **DENIED**. The supervisor's indication that the Office action of January 29, 2004, is withdrawn was improper and not based on a complete understanding of the record and is vacated. Further, as a consequence of failure to properly reply to a Final Office action this application stands abandoned. A Notice of Abandonment will be forthcoming.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number.

A handwritten signature in black ink, appearing to read "B. M. Kisliuk", with a stylized flourish at the end.

Bruce M. Kisliuk  
Director, Technology Center 1600



Atty. Dkt. No. 054707-0868

*IN THE UNITED STATES PATENT AND TRADEMARK OFFICE*

Applicants: Barbara S. SLUSHER et al.

Title: NAALADASE INHIBITORS FOR  
TREATING RETINAL  
DISORDERS AND GLAUCOMA

Appl. No.: 09/866,961

Filing Date: 05/30/2001

Examiner: Zohreh A. FAY

Art Unit: 1614

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AMENDMENT AND RESPONSE UNDER 37 CFR 1.111

Mail Stop NON-FEE AMENDMENT  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

This communication is responsive to the Non-Final Office Action dated February 14, 2003, concerning the above-referenced patent application. Since this communication is filed within the three month period for response, no extension of time is required.

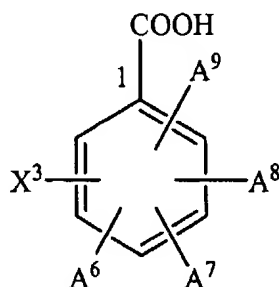
The amendments presented below are in compliance with the revised amendment format permitted in the Notice from the Office of Patent Legal Administration of the U.S. Patent and Trademark Office dated February 10, 2003, and published at 1267 OG 106 on February 25, 2003. Thus, the provisions of 37 CFR 1.121(a), (b), (c) and (d) are waived for amendments made in this application.

Please amend the application as follows.

Listing of Claims:

**Claims 1-24 (canceled)**

**Claim 25 (currently amended):** ~~The method of claim 1, wherein the NAALADase inhibitor~~  
is A method for treating retinopathy, age-related macular degeneration or glaucoma comprising  
administering to a mammal in need of such treatment an effective amount of a compound of  
 formula X



X

or an enantiomer or a pharmaceutically acceptable equivalent of said compound, wherein:

$X^3$  is  $-(CR^{36}R^{37})_nSH$ ,  $-O(CR^{36}R^{37})_2SH$ ,  $-S(CR^{36}R^{37})_2SH$  or  $-NR(CR^{36}R^{37})_2SH$ ;

$n$  is 1-3; and

$R$ ,  $R^{36}$ ,  $R^{37}$ ,  $A^6$ ,  $A^7$ ,  $A^8$  and  $A^9$  are independently hydrogen,  $C_1$ - $C_9$  alkyl,  $C_2$ - $C_9$  alkenyl,  $C_2$ - $C_9$  alkynyl, aryl, heteroaryl, carbocycle, heterocycle, halo, hydroxy, sulfhydryl, nitro, amino, cyano, isocyano, thiocyno, isothiocyno, formamido, thioformamido, sulfo, sulfinio,  $C_1$ - $C_9$  alkylsulfonyl,  $C_1$ - $C_9$  alkoxy,  $C_2$ - $C_9$  alkenoxy, phenoxy or benzyloxy, wherein said alkyl, alkenyl, alkynyl, aryl, heteroaryl, carbocycle, heterocycle, alkoxy, alkenoxy, phenoxy and benzyloxy are independently unsubstituted or substituted with one or more substituent(s).

**Claim 26 (original)** The method of claim 25, wherein the compound of formula X is selected from the group consisting of:

3-(2-mercaptoethyl)-benzoic acid;  
3-(mercaptomethyl)-benzoic acid;  
2-(mercaptomethyl)-benzoic acid;  
5-hydroxy-2-(2-mercaptoethyl)-benzoic acid;  
2-(2-mercaptoethyl)-benzoic acid;  
5-[(4-carboxyphenyl)methoxy]-2-(2-mercaptoethyl)-benzoic acid;  
2-(2-mercaptoethyl)-5-(phenylmethoxy)-benzoic acid;  
2-(carboxymethoxy)-6-(2-mercaptoethyl)-benzoic acid;  
5-[(3-carboxyphenyl)methoxy]-2-(2-mercaptoethyl)-benzoic acid;  
2-(2-mercaptoethyl)-6-(phenylmethoxy)-benzoic acid;  
2-[(2-carboxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-[(4-carboxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
3-(2-mercaptoethyl)-[1,1'-biphenyl]-2,3'-dicarboxylic acid;  
2-(3,3-dimethylbutoxy)-6-(2-mercaptoethyl)-benzoic acid;  
2-(2-mercaptoethyl)-6-(2-phenylethoxy)-benzoic acid;  
2-[(2-chlorophenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-[[3-carboxy-5-(1,1-dimethylethyl)phenyl]methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-(2-mercaptoethyl)-6-phenoxy-benzoic acid;  
2-(2-mercaptoethyl)-6-phenylamino-benzoic acid;  
2-(2-mercaptoethyl)-6-(phenylthio)-benzoic acid;  
5'-(1,1-dimethylethyl)-3-(2-mercaptoethyl)-[1,1'-biphenyl]-2,3'-dicarboxylic acid;  
3-(2-mercaptoethyl)-[1,1'-biphenyl]-2,4'-dicarboxylic acid;  
2-[(4-carboxy-2-methoxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-[(4-carboxy-3-methoxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-[(2-bromo-4-carboxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-[(3-bromo-4-carboxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-[(4-chlorophenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-(biphenyl-2-ylmethoxy)-6-(2-mercaptoethyl)-benzoic acid;

2-[(3-bromo-5-carboxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-[(2-bromo-5-carboxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-(2-mercaptoethyl)-6-[(4-methoxyphenyl)methoxy]-benzoic acid;  
2-(2-mercaptoethyl)-6-[(4-methylphenyl)methoxy]-benzoic acid;  
2-[(4-bromo-3-carboxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
2-[(2-carboxy-5-methoxyphenyl)methoxy]-6-(2-mercaptoethyl)-benzoic acid;  
5-(mercaptomethyl)-2-(2-phenylethoxy)-benzoic acid;  
2-bromo-5-(mercaptomethyl)-benzoic acid;  
4-(mercaptomethyl)-[1,1'-biphenyl]-2,3'-dicarboxylic acid;  
5-(mercaptomethyl)-2-(phenylmethoxy)-benzoic acid; and  
4-bromo-3-(mercaptomethyl)-benzoic acid; and  
enantiomers and pharmaceutically acceptable equivalents.

**Claims 27-49 (canceled)**

- Claim 50 (new):** The method of claim 25, wherein the method is for treating retinopathy.
- Claim 51 (new):** The method of claim 50, wherein the retinopathy is diabetic retinopathy.
- Claim 52 (new):** The method of claim 25, wherein the method is for treating age-related macular degeneration.
- Claim 53 (new):** The method of claim 25, wherein the method is for treating glaucoma.
- Claim 54 (new):** The method of claim 26, wherein the method is for treating retinopathy.
- Claim 55 (new):** The method of claim 54, wherein the retinopathy is diabetic retinopathy.
- Claim 56 (new):** The method of claim 26, wherein the method is for treating age-related macular degeneration.
- Claim 57 (new):** The method of claim 26, wherein the method is for treating glaucoma.

**Claim 58 (new):** A method for treating retinopathy or age-related macular degeneration comprising administering an effective amount of a NAALADase inhibitor to a mammal in need of such treatment.

**REMARKS**

Claims 1-24 and 27-49 are cancelled and claim 25 is amended to remove non-elected subject matter. New claims 50-58 are added. Upon entry of the foregoing amendments, claims 25, 26 and 50-58 would be pending.

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and in view of the reasons which follow.

**35 U.S.C. 102(e)**

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Meyerhoff et al. In support of this rejection, the Office action states: "Meyerhoff et al. Teach [sic] the use of a NAALADase inhibitor for the treatment of glaucoma."

The foregoing amendments obviate this rejection.



### CONCLUSION

Applicants believe that this application is now in condition for allowance. Favorable reconsideration of this application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of this application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date May 12, 2003

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